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Open Letter to Ontario Premier and Deputy Premier/Minister of Health

Premier's Office
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Dear Premier Ford and Deputy Premier/Minister of Health Elliott:

We are writing this as an open letter to you because we are concerned that you are not aware of our previous communications detailing the perspectives of patients and clinicians whom we represent. A policy being considered by your government may present risks to some patients who will be forced to switch from a biologic medicine that is working well to a non-identical biosimilar, which evidence shows can have negative health consequences.

The policy development process has been disingenuous from the outset, lacking meaningful engagement of the patients who will be directly impacted. Patient group representatives were actually asked to sign a non-disclosure agreement precluding consultation with their own members, just to hear the government's position. This is entirely inappropriate. We declined to sign this document because it would be unethical and a violation of our members' trust for us to enter into such an agreement. We are, specifically, the Canadian Organization for Rare Disorders, Crohn's and Colitis Canada, Diabetes Canada, Gastrointestinal Society, and the Institute for Optimizing Health Outcomes. We are all representatives of key stakeholders and all "non-signers."

Secondly, the Canadian Agency for Drugs and Technologies in Health (CADTH), under contract with the pan-Canadian Pharmaceutical Alliance (pCPA), hosted a "closed" consultation extended to only select patient groups and other stakeholders. It is not transparent how certain groups were selected, or why some groups were not. As troubling, the experts who presented to the groups described "options" that were promoting a non-medical switching policy. Moreover, the consultation was hosted in November with findings to be presented to governments at the end of January. This consultation was supposedly to help provinces develop the best policy. It was surprising to our groups that many provinces (BC, Alberta, Manitoba) had already made their policy decisions, with announcements prior to and during the

consultation process which of course, calls into question the authenticity of the consultation. Even your own department in Ontario has concluded its consultation with only a single policy option and developed a briefing document with a recommendation around that option, in advance of the final CADTH report. We have engaged with governments and national organizations in good faith, with the intention to provide our best advice to achieve improved patient outcomes. Our good faith has been violated.

We are writing to ask you to restore that faith by listening to our concerns and considering all policy alternatives.

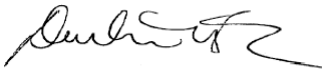
We would like to reiterate several points that have not been adequately discussed and explored in government's consultation process.

- No other developed country has adopted a universal mandatory switching of all patients who are stabilized on specific biologics to a biosimilar medicine. Some countries cite ethical concerns of taking away clinicians' ability to prescribe the best medicine for individual patients. Other countries acknowledge the risks to a secure supply of biologic medicines with a reliance on a single (biosimilar).
- Almost every other developed country has implemented multi-pronged strategies that seek to balance lower biologic drug budgets, security of supply, and clinician/patient consultation.
- There is sparse research or, more accurately, almost no research and evidence, as to the long-term safety and impact of non-medical switching for the diabetes, inflammatory bowel diseases, and even for rheumatoid arthritis and other inflammatory joint diseases.
- Most clinicians – with extensive medical training and experience – oppose a mandatory switch policy. Take note, this does not mean that clinicians oppose switching therapy. A switch for some patients may be safe and effective and could be encouraged. However, this must be done in the right way, a way that respects the patients' individual circumstance, and physician clinical assessment and experience.
- Surveys conducted with Canadian patients show they are concerned about the potential impact of a forced switching policy on health outcomes. In Canada, they are concerned about disruption in their patient support programs which often go hand in hand with some biologic medicines.
- Research shows that patients who experience anxiety and distress and/or lack of confidence in their medication tend not to adhere to their treatment regimen, which leads to poorer outcomes and higher use of other healthcare resources. Anxiety about a forced switch can be avoided when the vision to enhance biosimilar uptake and reduce costs is coupled with patient perspectives.
- The security of medication supply and ability to meet patient needs are vulnerable when there is any single supplier, which is what will result from a biosimilar exclusive policy. Moreover, a single supplier of any medicine negates any future competition and additional price savings.

As representatives of patients, we want to support healthy public policy, while ensuring these policies support access to the medicines that best suit individual patient needs. We recognize the need to contain costs. However, cost containment can be achieved through measures that include education, practice support, feedback mechanisms, and alternative policy measures. Forced non-medical switching appears to be the only option being considered, even though it is not the only option. We urge you to be innovative in developing policies to meet your departments stated goals to offer patients therapy in a cost-effective way, and to enhance the biosimilar market. We encourage you to lead the development of alternative strategies to meet these goals without taking away treatment for patients who are stable on their treatment regimen, thereby risking their health.

We seek the opportunity to meet with you directly to provide our patient perspectives, our expert opinions, and our recommendations for a balanced and sustainable biologics/biosimilars policy.

Thank you,



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